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## 2. Improper Withdrawal of Claims

The Office Action fails to acknowledge or respond to Applicants' request for reconsideration of the withdrawal of claims 19-23 and 30-34. Accordingly Applicants hereby renew the request for examination of all pending claims. The withdrawal of claims 19-23 and 30-34 is improper in view of the allowance of compound claim 1, having the same scope as the withdrawn process and method claims. The Office Action fails to provide any reasons for maintaining the withdrawal of these claims. Applicants respectfully remind the Examiner that the previous Office Action acknowledges that the withdrawn claims would be re-joined upon allowance of subject matter of the same scope. See Examiner's remarks, Office Action mailed 4 December 2001, paper no. 8, page 2. Applicants respectfully request that examination of all currently pending claims proceed.

### Section 112, First Paragraph Rejections Overcome

Claims 26-27 currently stand rejected under 35 U.S.C. §112, first paragraph, the Office Action stating that the specification does not provide enablement for all of the various recited diseases many of which are unrelated. Applicants respectfully traverse this rejection.

Applicants' respectfully point out that the Examiner has not provided the objective evidence necessary to establish non-enablement. Specifically, the Office Action does not provide any reason why one of skill in the art would reasonably doubt that the formulations and routes of administration described by Applicants would be suitable to teach how to use the claimed compounds for one condition but not another. The burden is on the Examiner to provide objective evidence establishing why one skilled in the art would reasonably doubt the applicability of this teaching to the treatment of one condition over another. In the absence of such evidence, the Office Action fails to meet its burden with respect to the enablement rejection.

Applicants further respectfully submit that an analysis of all of the Wand's factors indicates that the pending claims satisfy the enablement requirement of section 112, first paragraph. In particular, with respect to the state of the prior art, the Office



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Action fails to address the documentary evidence previously submitted by Applicants which establishes that it is known in the art that the various conditions recited in Applicants' claims are indeed related in that they are all known to be mediated by COX-2. See, USPN 5,474,995 a copy of which was previously provided. The Office Action fails to explain why, given the state of knowledge in the art, the Examiner continues to take the position that the recited conditions are unrelated. The Examiner's position directly contradicts the knowledge in the art.

The analysis of the remaining Wand's factors further supports Applicants' position that the pending claims are fully enabled. The nature of the invention is in the treatment or prophylaxis of a condition or disease, specifically a condition or disease mediated by COX-2. The breadth of the claims is consistent with the level of skill and knowledge in the art as to the types of conditions and diseases which are known to be mediated by COX-2. See USPN 5,474,995. A clinician of ordinary skill in this art is familiar with the various conditions and diseases mediated by COX-2 and typical dosing strategies for treating and preventing the same. With regard to the fifth Wand's factor, the Examiner has argued that the level of predictability regarding COX-1 and COX-2 is low. While this is may be true in the abstract, the instant application contains a working example and biological data demonstrating that the instantly claimed compounds selectively inhibit COX-2, thus removing this uncertainty. Applicants' specification further provides ample guidance with respect to how to formulate and administer the claimed compounds and the various conditions and diseases for which they are useful. See pages 7-11, line 23 of Applicants' specification. Applicants have also provided working examples of both how to make the claimed compounds and how to evaluate their biological activity as selective COX-2 inhibitors. Finally, Applicants respectfully submit that undue experimentation would not be required to use the claimed compounds for the recited purposes, in view of the ample disclosure provided by Applicants' and the level of skill in the art. Accordingly it is respectfully submitted that analysis of the Wands' factors indicates that the instantly pending claims are in compliance with section 112, first paragraph.

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Applicants further respectfully traverse the Examiner's position that "there is no indication that the claimed compound would have the alleged properties." The instant application contains biological data establishing that the instantly claimed compounds are selective COX-2 inhibitors. See, page 35 of Applicants' specification. It is well known in the art that COX-2 inhibitors are useful for the treatment of conditions and diseases mediated by COX-2. See USPN 5,474,995 and Physician's Desk Reference entries for VIOXX® and CELEBREX®, two currently marketed COX-2 inhibitors. The Examiner is further cautioned that is not the province of the PTO to determine whether a drug is effective for a particular disease. MPEP 2107.02.

For all of the foregoing reasons, the instantly pending claims satisfy the requirements of section 112, first paragraph and withdrawal of this rejection is respectfully requested.

Section 112, Second Paragraph Rejection Overcome

Claim 28 Currently stands rejected under 35 U.S.C. Section 112, second paragraph, the Office Action stating that the claims are indefinite for use of the term "pain." Applicants respectfully maintain the traversal of this rejection.

The Examiner appears to be concerned that Applicants have labeled pain a "disease." Claim 28 is directed toward methods for the treatment or prophylaxis of pain. Claim 28 does not state that pain is a disease. In fact, the claims of the instant application are directed toward methods for the treatment or prophylaxis of a condition or disease; they are not limited to treating only disease. However, whether pain is artificially labeled a "manifestation" as the Office Action suggests, is not relevant to the definiteness inquiry; labeling pain a manifestation does not satisfy the Examiner's burden of explaining why one skilled in the art would not understand the meaning of the term, particularly in light of the fact that it is in common usage.

The term "pain" is in common usage and employed by Applicants in a manner consistent with its ordinary meaning. There is no limitation as to the particular type of pain encompassed by claim 28 and none is intended. In fact, Applicants intend that

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claim 28 should encompass the treatment or prophylaxis of any type of pain with a compound of claim 1. Accordingly, given that Applicants have employed a term in common usage in a manner consistent with its ordinary meaning, the claim language is in compliance with section 112, second paragraph and withdrawal of this rejection is respectfully requested.

Outstanding Formalities

Applicants have on two occasions requested a fully initialed copy of the PTO Form-1449 mailed 28 September 2001. Such copy was not provided with the outstanding Office Action. The Examiner is respectfully requested to consider the cited references and return a duly initialed copy of the PTO Form-1449 with the next communication.

Applicants respectfully submit that the instant application is in condition for allowance, which action is respectfully requested. The Examiner is invited to contact the undersigned at 483-8222, to discuss this case further if desired.

Respectfully submitted,



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